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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,337	11/14/2003	Ronald Lynn Merriman	PC20550A	9853

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AGOURON PHARMACEUTICALS, INC.
10777 SCIENCE CENTER DRIVE
SAN DIEGO, CA 92121

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,337	MERRIMAN, RONALD LYNN	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/6/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

Claims 1-15 are pending.

Claims 1-15 are rejected.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 6, 2004 has been acknowledged.

Claim Rejections - 35 USC § 112-second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1--4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear from the claim language what MEK inhibitor the applicant is referring to. The claim should include at least one of the limitations in the instant claims 6 or 9.

Claim Rejections - 35 USC § 112-First paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating colon cancer, does not reasonably provide enablement for all solid tumor-cancers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention the invention commensurate in scope with these claims. For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention, 2) State of prior art, 3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure, 4) Level of predictability in the art, 5) Amount of direction and guidance provided by the inventor, 6) Existence of working examples 7) Breadth of claims and 8) Level of ordinary skill in the art.

1) Nature of invention: the claim is drawn to a method of treating cancer by administering but in view of the example in the specification (see page 21 lines 26-32) indicates partial tumor responses.

2) The state of the prior art: The data (see page 21 lines 26-32) suggests that treating cancer requires an undue amount of research to successfully attain that goal. There is currently no completely effective therapy for the treatment of all types of cancer and definitely no magic drug to treat all types of cancer. A search for therapeutic agents useful for the treatment of cancer is ongoing.

3) The predictability or lack thereof in the art: On page 1 of applicants' specification lines 17+ shows that "In tumors, the pathway appears to be the single most important pathway for the transmission of mitogenic signals from the plasma membrane to the nucleus. As disclosed above, there is no absolute predictability even in view of the seemingly high level of skill in the art. Firstly, for a compound or genus to be effective against all types of cancer generally is contrary to medical science. Cancer is a process that can take place in virtually any part of the body. There is a vast range of forms that it can take, causes for the problem, and biochemical pathways that mediate the disease. There is no common mechanism by which all, or even most, cancer arise. Accordingly, treatments for diseases associated with cancer are normally tailored to the particular type of cancer present, as there is no, and there can be no "magic bullet" against all types of cancer.

5) Amount of direction and guidance provided by the inventor.

The amount of direction or guidance present is found on pages 13-30 wherein *mouse clone carcinoma* was used to identify and evaluate the treatment of cancer/tumors. Treating lung cancer does not constitute treating all types of cancer/tumor. However, that embraces a myriad of conditions.

6) Existence of working examples.

As discussed above, working example is found on pages 13-30. Applicant's limited working example for all types of cancer does not enable one of skill in the art to treat the numerous amounts of diseases encompassed by the instant invention.

7) Breadth of claims.

Claim 1 is extremely broad due to the vast number of possible cancers encompassed by the instant invention.

8) Level of ordinary skill in the art.

The level of skill in the art is high. Due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Hence, the specification fails to provide sufficient support of the broad use of the compounds of the claims for the treatment of all cancers. As a result necessitating one of skill in the art to perform an exhaustive search to determine which cancer can be treated by what compounds of the instant claims in order to practice the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKearn et al., US 6,858,598 in view of Bearnett et al., US 2004/0102360 A1 and Coleman et al., US 2005/0234080 A1.

McKearn et al. teach the current claim 1 method of treating cancer in mammals by administering a combination of comprising matrix metalloproteinase inhibitor (see col. 4 lines 52-63) and capecitabine (see col. 46 lines 1). Administering a therapeutic effective amount in the instant claim 1 is recited (see col. 8 lines 52+), wherein the cancer is lung as recited in the instant claim 5 (see col. 11 lines 16-20).

With regards to claim 2, the MEK inhibitor and capecitabine is administered simultaneously (see col. 9 line 15-20).

McKearn et al. did not explicitly teach a MEK inhibitor, as in the current claim 1, however, it is known to one of ordinary skill in the art that matrix metalloproteinase inhibits angiogenesis regardless of the pathway as they inhibit formation of new blood vessels. The McKearn reference did not per se teach administering the capecitabine before MEK inhibitor, nor the administration of capecitabine after the MEK inhibitor. However, the McKearn reference teaches (see col. 9 lines 32-34) that the sequence in which the therapeutic agents are administered is not narrowly critical.

Barnett et al. teach the current claim 1 a method of treating cancer in mammals by administering a combination of comprising of a MEK inhibitor (see ¶ 0070) and capecitabine (see ¶ 0118) are administered simultaneously as recited in the current claim 2 (see ¶ 0032).

Coleman et al teach the MEK inhibitor is CI-1040 (see ¶ 0032) as recited in the current claims 6-8.

The above McKearn et al. reference teaches a method of treating cancer by administering a matrix metalloproteinase inhibitor with capectibine. The claims differ

from the reference by using a different inhibitor. However, one of ordinary skill in the art would have been motivated to employ the inhibitor of Coleman et al. because it is a MEK inhibitor with the expectation of obtaining the desired result of compounds that inhibit signal transduction cascades downstream of ras- kinase. With regard to the administration of MEK inhibitor before or after capectibine, it is well within the level of the skill in the art to determine in what sequence the drugs are administered as taught by McKearn et al. (see supra) hence the reference makes obvious the instant application.

Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrett et al., US 6,960,614 B2 in view of Coleman et al., US 2005/0234080 A1 and Barnett et al., US 2004/0102360 A1 as applied to claims 1-10 above, and further in view of McKearn et al., US 6,858,598.

Barrett et al., Coleman et al., and Barnett et al are applied here as stated in the above rejection. In addition Barrett et al. teach the MEK inhibitor is The method of Claim 11, wherein the MEK inhibitor is N-((R)-2,3-dihydroxy-propoxy]-3,4-difluro-3-4-difluoro-4-iodo-phenylamino)-Benzamide (see col. 4 lines 60-61) wherein the cancer is lung (see col. 49 lines 27-35) in the instant claim 15.

Coleman et al teach the MEK inhibitor is CI-1040 (see ¶ 0032) as recited in the current claims 12 and 13.

Barnett et al. teach the current claims 11 and 12 a method of treating cancer in mammals by administering a combination of comprising of a MEK inhibitor (see ¶ 0070) and capecitabine (see ¶ 0118).

McKearn et al. teachings are applied here as indicated above a method of treating cancer in mammals by administering a combination of comprising a matrix metalloproteinase inhibitor (see col. 4 lines 52-63) and capecitabine (see col. 46 lines Administering a therapeutic effective amount is recited (see col. 8 lines 52+), wherein the cancer is lung as recited in the instant claim 15 (see col. 11 lines 16-20).

Although the above mentioned references combined did not per se teach the sequence of administration, however it is taught in the McKearn reference that (see col. 9 lines 32-34) the sequence in which the therapeutic agents are administered is not narrowly critical, therefore it is well within the level of the skill in the art to determine in what sequence the drugs are administered as taught by McKearn et al. hence the reference makes obvious the instant application.

Thus, the claimed invention was prima facia obvious to make and use at the time it was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
1/24/06

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600